

APR 28 2010

U.S. Serial No. 10/601,171

Filing Date: June 23, 2003

PROPOSED CLAIM AMENDMENT
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FOR DISCUSSION PURPOSES

61. (Currently Amended) A composition comprising an amount of an isolated monoclonal antibody effective to ~~prevent~~ prophylactically or therapeutically treat staphylococcal infection in neonates and a pharmaceutically acceptable carrier, wherein the antibody specifically binds to poly-glycerol phosphate of Lipoteichoic acid (LTA) of Staphylococcus ~~Gram-positive bacteria~~ and is of the IgG isotype, wherein the antibody binds to and enhances opsonization of multiple serotypes of *Staphylococcus epidermidis*, coagulase negative staphylococci, *Staphylococcus aureus* and *Streptococcus mutans* by phagocytic cells with or without complement as compared to an appropriate control in an in vitro opsonization assay.

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APPENDIX OF
PRESENTLY PENDING CLAIMS

61. A composition comprising an amount of an isolated monoclonal antibody effective to prevent staphylococcal infection in neonates and a pharmaceutically acceptable carrier, wherein the antibody specifically binds to poly-glycerol phosphate of Lipoteichoic acid (LTA) of Gram positive bacteria and is of the IgG isotype, wherein the antibody binds to and enhances opsonization of multiple serotypes of *Staphylococcus epidermidis*, coagulase negative staphylococci, *Staphylococcus aureus* and *Streptococcus mutans* by phagocytic cells with or without complement as compared to an appropriate control in an in vitro opsonization assay.

62. The composition of claim 61, wherein the opsonization assay is performed in the presence of complement, phagocytic cells, or both.

63. The composition of claim 62, wherein the complement or cells or both are human in origin.

65. The composition of claim 62, wherein the phagocytic cells comprise macrophages, monocytes, neutrophils, or combinations thereof.

66. The composition of claim 62, wherein opsonization is measured by determining opsonophagocytic bactericidal activity.

77. A composition comprising a monoclonal antibody which specifically binds to poly-glycerol phosphate of LTA of Gram positive bacteria, or antigen binding fragment thereof, and a pharmaceutically acceptable carrier, wherein the monoclonal antibody comprises the

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complementarity determining regions (CDRs) of the heavy and light chain variable regions of monoclonal antibody 96-110 set forth as SEQ ID NO:87 and SEQ ID NO:89.

79. The composition of claim 61 or 77, wherein the antibody comprises a portion of a human antibody sequence.

80. The composition of claim 79, wherein the portion of human antibody sequence comprises an Fc region.

81. The composition of claim 61 or 77, wherein the antibody specifically binds LTA exposed on the surface of the cell wall of Gram positive bacteria.

86. The composition of claim 61 or 77, wherein the antibody binds to serotype 5, serotype 8, or both serotype 5 and serotype 8 of *Staphylococcus aureus*.

87. The composition of claim 61 or 77, wherein the antibody additionally specifically binds to LTA of *Streptococcus faecalis* or *Streptococcus pyogenes*.

91. The composition of claim 61 or 77, wherein the antibody reduces LTA-mediated inflammation, LTA-mediated cytokine production, or combination thereof.

93. The composition of claim 77, wherein the antibody is an Fab, Fab', F(ab')₂, or sFv fragment of an antibody.

94. The composition of claim 61 or 77, further comprising at least one additional monoclonal antibody having specificity for LTA.

95. A pharmaceutical composition comprising an effective amount of an antibody of claim 77, for use in a human neonate.

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104. A composition comprising a monoclonal antibody which specifically binds to poly-glycerol phosphate of LTA of Gram positive bacteria, or antigen binding fragment thereof, and a pharmaceutically acceptable carrier, wherein the monoclonal antibody comprises the heavy chain variable region set forth as SEQ ID NO:87.

105. A composition comprising a monoclonal antibody which specifically binds to poly-glycerol phosphate of LTA of Gram positive bacteria, or antigen binding fragment thereof, and a pharmaceutically acceptable carrier, wherein the monoclonal antibody comprises the light chain variable region set forth as SEQ ID NO:89.

106. A composition comprising a monoclonal antibody of claim 61, wherein the monoclonal antibody comprises a heavy chain comprising the heavy chain complementarity determining regions (CDRs) of the monoclonal antibody 96-110 and a variable region having 80% amino acid identity with SEQ ID NO:87.

107. The composition of claim 106, wherein the variable region has 85% amino acid identity with SEQ ID NO:87.

108. The composition of claim 106, wherein the variable region has 90% amino acid identity with SEQ ID NO:87.

109. The composition of claim 106, wherein the variable region has 95% amino acid identity with SEQ ID NO:87.

110. A composition comprising a monoclonal antibody of claim 61, wherein the monoclonal antibody comprises a light chain comprising the light chain complementarity determining regions (CDRs) of the monoclonal antibody 96-110 and a variable region having 80% amino acid identity with SEQ ID NO:89.

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111. The composition of claim 110, wherein the variable region has 85% amino acid identity with SEQ ID NO:89.

112. The composition of claim 110, wherein the variable region has 90% amino acid identity with SEQ ID NO:89.

113. The composition of claim 110, wherein the variable region has 95% amino acid identity with SEQ ID NO:89.

114. A composition comprising a monoclonal antibody of claim 61, wherein the monoclonal antibody comprises a heavy chain comprising the complementarity determining regions (CDRs) of the monoclonal antibody 96-110 heavy chain variable region set forth as SEQ ID NO:87 and having at least 70% amino acid identity with the monoclonal antibody 96-110 heavy chain variable region set forth as SEQ ID NO:87.

115. A composition comprising a monoclonal antibody of claim 61, wherein the monoclonal antibody comprises a light chain comprising the complementarity determining regions (CDRs) of the monoclonal antibody 96-110 light chain variable region set forth as SEQ ID NO:89 and having at least 70% amino acid identity with the monoclonal antibody 96-110 light chain variable region set forth as SEQ ID NO:89.

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